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September 24, 1999

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-3059: CFSAN Priorities for FY 2000

The Board of Directors of the Association of Food and Drug Officials (referred to henceforth as "AFDO") is pleased to provide the following comments to the U.S. Food and Drug Administration regarding FY 2000 priorities for the Center for Food Safety and Applied Nutrition (CFSAN).

AFDO is the preeminent organization in the U.S. of federal, state, and local regulatory officials, having promoted science-based food safety through the development of model laws and regulations and providing uniform training over its 103 year history. Regulated industry encompasses almost 50 percent of the membership of AFDO. During the past two years AFDO has advocated an integrated food safety system for the U.S. to eliminate duplication and gaps in our current system of regulating foods. It is therefore with this perspective that AFDO provides the following comments. Further, many of AFDO's comments to FDA in June of 1998, regarding CFSAN priorities for FY'99 are still pertinent. A copy of those comments are included herewith for review.

AFDO believes that CFSAN must remain a leader in utilizing the best science available for all decisions made with respect to food safety. This includes interpretations of current law and regulations, as well as in the development of new regulations. AFDO is concerned that Congressional imposition of additional responsibilities has severely diluted CFSAN's abilities to respond in a timely fashion to both industry and state/local requests for interpretations and assistance. We strongly believe that the single most important priority for CFSAN should be to devote adequate resources to **both** the development of science-based regulatory approach to food safety, encompassing new and developing technologies, **and** in responding to requests for interpretations and assistance regarding current policies

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and regulations. In a fully integrated national food safety system, industry and the state and local jurisdictions must be able to rely on FDA for timely responses to such requests. Uniformity demands it, since it is only through timely science-based responses that we can ensure uniformity throughout the country. And uniformity is one of the key elements of a system envisioned by AFDO and so many others. The states should be equal partners in such a system and should be able to rely on FDA to fulfill its part in the system.

With this said, AFDO believes that streamlining the decision-making processes within CFSAN is necessary to make such a system a reality. The word we find commonly used to describe this is "empowerment." We believe CFSAN must empower its employees to make decisions that both FDA and the states can rely on to be sound and science-based. If FDA believes that this is not currently possible, FDA needs to put more emphasis on human resources by hiring the staff it believes can make these types of decisions. At the same time, FDA should not shy away from utilizing the knowledge and expertise available from other sources, including the states and regulated industry.

As FDA knows from previous experience, premarket review and approval of food and dietary supplement ingredients must continue to be a priority. Congress and industry would have it no other way, and the states and the citizens of the U.S. must continue to rely on FDA to ensure that unsafe ingredients are not present in our food supply.

In this vein, AFDO believes that too little resources are currently being devoted to the safety and labeling of dietary supplements. AFDO seriously doubts that the Dietary Supplement Health and Education Act (DSHEA) will be revised any time soon to require industry to substantiate safety prior to the marketing of products. Therefore, it is extremely important that Americans be able to rely on FDA to eliminate unsafe products from the marketplace as expeditiously as possible. During a recent AFDO training workshop on dietary supplements, an official from the Council for Responsible Nutrition advocated a process by which industry itself could assist FDA in identifying unsafe and/or inappropriately labeled products. AFDO encourages FDA to take industry up on this offer. Also, adoption of Good Manufacturing Practices for supplements should be given high priority, along with adoption of regulations which better define "disease" or "disease-related condition" and acceptable versus misleading structure/function claims.

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As we are all aware, because of staffing shortages FDA has had to continually move staff around to "put out fires" caused by shifting priorities, more or less due to interventions from Congress, Government Accounting Office reports, and pressure from other outside interests. Perhaps now is the time for FDA to "take some lumps" from one or more of the aforementioned, and remain focused on the real problems associated with food safety. Political pressures aside, the time has passed for CFSAN to be all things to all people. If Congress wishes FDA to adequately address the many priorities it places on FDA, Congress should see to it that FDA is adequately staffed to do so. In the meantime, though, CFSAN is doing the right thing by trying to prioritize its activities through consensus building.

In a related matter, it is our understanding that FDA continues to collect *adverse event reports and is devoting more resources to review these reports.* Given the pressures from industry and Congress to ensure that the reports are meaningful, FDA should continue to rely on these reports, once reviewed, in making science-based decisions regarding the safety of foods and supplements.

In the area of domestic regulation of foods, AFDO believes that FDA should not abandon the *universal HACCP* approach, which would require all food manufacturers to conduct a risk assessment and utilize HACCP as necessary to control hazards. The resources FDA (and USDA) has devoted to separate regulations for separate food industries could be better devoted to the development of a universal Hazard Analysis Critical Control Point regulation for all processed foods. AFDO understands our associate members' aversion to "additional regulation" when many of the larger food processors in the U.S. are using HACCP principles to produce safe foods. However, there are many smaller food processors (9,000 in one state alone) who could benefit from a requirement to conduct a hazard analysis, even if no critical control points are identified.

Other domestic areas AFDO believes should be of high priority includes emphasis on detecting undeclared allergens in the food supply, which are the subject of more and more recalls. Although it is difficult to balance urgent acute issues with more chronic health and long term concerns, CFSAN should give priority to this issue.

In the international arena, FDA should continue to insist that Codex adopt science-based standards and model regulations, which do not lower and dilute our U.S. food safety standards. At the same time, we should continue to insist that the European Union and other outside interests also rely on good science as the basis for commerce

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throughout the world, including acceptance of genetic engineering of foods and crops where safety is not in question. FDA must have an import program in place that assures consumers of the equivalency in the safety of imports. This should remain a very high priority for the agency as a whole, especially in light of recent high profile foodborne outbreaks and contaminated food associated with imports.

Given the retirements and other personnel changes within CFSAN, along with the resource cuts experienced during the last thirty years in real dollars, FDA must make a major thrust to rebuild the expertise within CFSAN and ensure that this valuable Center receives a fair share of funding. CFSAN should continue to utilize the resources of JIFSAN on risk assessment and research issues, and with USDA and the Center for Veterinary Medicine on the issue of antimicrobial resistence. In fact, nearly all of the priorities CFSAN identified for FY'99 continue to applicable to FY 2000.

Further, AFDO believes there are untapped resources in the states to assist FDA with oversight of imported foods. It is good that FDA is streamlining the current system and devoting more human resources in this area, but the states are ripe for additional partnerships. State sampling and oversight of imported foods in domestic commerce remain viable complementary activities to FDA's oversight at the borders.

AFDO also believes that the creation of a fully integrated food safety system for this country must include collaboration among the various federal agencies. CFSAN must therefore continue to work closely with USDA's Food Safety and Inspection Service, the Centers for Disease Control, and the Environmental Protection Agency, to name a few, to eliminate duplication and ensure that the safety of our food supply does not suffer from territorial issues. We would encourage the other agencies to do the same.

Finally, AFDO is convinced that there are many as yet untapped areas for CFSAN collaboration with her state counterparts through contracts, partnerships, and work-share arrangements, without such activities bordering on "unfunded mandates." AFDO encourages FDA to develop additional mechanisms to utilize state and local government resources, and for funding to the states to conduct some of the activities which FDA cannot reasonably be expected to do for lack of human resources. Our understanding is that the Roles and Responsibilities Work Group of the National Food Safety System project is developing a model partnership agreement that could be used as a basis for new or expanded activities in this area.

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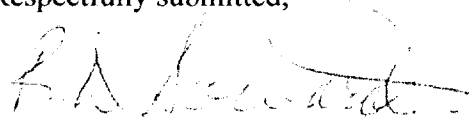
AFDO wishes to thank CFSAN for the opportunity to provide these comments on priorities for FY 2000, and hopes that these comments will assist in setting priorities that will translate into an increased level of safety for foods, food additives, and supplements produced and distributed in the U.S.

Respectfully submitted,



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Enclosure